

1 has been amended to recite "A biologically pure strain of *Lactobacillus plantarum*, strain LB931".

Claims 2, 10 and 11 were rejected under 35 USC §101 for containing the recitation of a "use". Claims 2, 10 and 11 have been cancelled. The subject matter of claims 2, 10 and 11 may now be found in new claims 15-23. New claims 15-23 are directed to method claims.

Claims 2, 4, 5 and 7-11 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite.

Claims 4 and 7 were objected to for containing the term "characterized in that". While it is respectfully submitted that the term "characterized in that" is definite, and in the interest of advancing prosecution, the transitional phrase of claims 4 and 7 has been amended.

In the outstanding Official Action, claims 5 and 8 were rejected for containing the term "preferably  $10^5$  to  $10^9$  cfu". Claims 5 and 8 have been amended to remove this terminology. Claims 12 and 14 have been added to recite a pharmaceutical or absorbent product that contains  $10^5$  to  $10^9$  cfu of *Lactobacillus plantarum* strain LB931.

Claims 7, 10 and 11 were rejected for allegedly being indefinite for containing the phrase "such as". As noted above, claims 10 and 11 have been cancelled. Claim 7 has been amended to remove the term "such as". Claim 13 has been added to recite an absorbent product which is selected from the group consisting

of a feminine hygiene product, a diaper, a sanitary napkin, a panty garter and an incontinence guard.

In light of the changes to claims 2, 4, 5 and 7-11, it is respectfully submitted that these claims are now definite to one of ordinary skill in the art.

In the outstanding Official Action, claims 1-11 were also rejected under 35 USC §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the present invention. The outstanding Official Action noted that a deposit was made under the terms of the Budapest Treaty. The outstanding Official Action required an affidavit or declaration by applicants or a statement by an attorney of record stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent. Applicants hereby present a Declaration of Availability and Maintenance of Microorganism. The declaration establishes that all restrictions imposed by the depositor on availability to the public of the deposited material will be removed upon issuance of the present application.

The outstanding Official Action also noted that the specification must also state the date of deposit, the number granted by the depository and the name and address of the

depository. As such, the present specification has been amended to recite the date of deposit, and the name and address of the depository.

Claims 1-6, 9 and 10 were rejected under 35 USC §102(b) as allegedly being anticipated by or under 35 USC §103 as allegedly being obvious over BRUCE et al. (U.S. Patent No. 5,705,160) or REID et al. (U.S. Patent 5,645,830). The outstanding Official Action stated that the cited patents disclose strains of *L. plantarum*. The outstanding Official Action alleged that the strains of the cited patents share the same genus and species designation and would likely exhibit the same properties. However, this rejection is respectfully traversed.

It is respectfully submitted that the *L. plantarum*, LB931 strain of the present invention, is distinct from the cited patents. The LB931 strain of the present invention is a novel strain of *Lactobacillus plantarum*. The bacterial strain of the present invention is valuable for preventing and/or treating urogenital infections as it inhibits growth of a large number of pathogenic microorganisms. The LB931 strain of the present invention has a long shelf life, is resistant to therapeutic concentrations of antibiotic substance and spermicidal compounds, and is easily transferred to the human skin. Thus, it is respectfully submitted that the strain of the present invention exhibits unexpected, improved and distinct properties.

In fact, the specification provides evidence of the distinct properties of strain LB931. The Examiner's attention is respectfully directed to the present specification beginning on page 7, wherein the examples of the present invention are provided.

While it is respectfully submitted that the present specification distinguishes the LB931 strain from the *L. plantarum* strains set forth in the cited patents, a declaration has been provided by Maria ISAKSSON providing evidence of the differences between the strain of the present invention and the cited patents. Maria ISAKSSON is a third party declarant.

The declaration by Maria ISAKSSON provides that the LB931 strain is distinct from the strains of the cited patents. The strain of the present invention has an enhanced ability to inhibit growth and kill pathogenic material. The declaration provides experimental results which illustrate the advantages of using *Lactobacillus plantarum* LB931, over the *L. plantarum* strain ATCC 8014 set forth in the 5,705,160 patent.

It is also noted that Maria ISAKSSON also attempted to provide comparative data for the strain of the present invention relative to *L. plantarum* ATCC 55883 set forth by REID et al. in the 5,645,830 patent. However, the *L. plantarum* ATCC 55883 strain was not available. As evidence of the unavailability of the strain, applicants also provide a statement that the ATCC 55883 *Lactobacillus plantarum* is a restricted item, on regularity

hold.

Claims 7, 8 and 11 were also rejected under 35 USC §103 as allegedly being obvious in view of the cited patents noted above and further in view of WO 97/02846. The outstanding Official Action conceded that the cited patents failed to teach an absorbent article comprising *L. plantarum*. In an effort to remedy the deficiencies of the cited patents, the outstanding Official Action adds WO 97/02846 to the rejection. However, it is respectfully submitted that the WO 97/02846 publication fails to remedy the deficiencies of BRUCE et al. and REID et al. As noted in the present specification and in the declaration of Maria ISAKSSON, the *Lactobacillus plantarum* strain of the present invention, LB931, is a novel strain. As the claimed invention is directed to a novel strain of *Lactobacillus plantarum*, it is respectfully submitted that the cited patents fail to anticipate or render obvious the present invention.

In view of the present amendment and the foregoing remarks, therefore, it is believed that this application has been placed in condition for allowance, as amended. Allowance and passage to issue on that basis are accordingly respectfully requested.

GRAHN HAKANSSON et al. S.N. 09/623,562

Attached hereto is a marked-up version of the changes made to the specification and claims. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

IN THE SPECIFICATION:

Page 4, the paragraph beginning on line 14 has been amended as follows:

--A novel strain of *Lactobacillus plantarum*, referred to as LB931, has been isolated, which fulfils requirements listed above. The strain has been deposited on January 27, 1998 at [Deutsche Sammlung von Mikroorganismen, Braunschweig, DE] Dsmz-Deutsche Sammlung von Mikroorganismen und Zellkulturen, Mascheroder Weg 1b D-38124 Braunschweig. It has been assigned accession number DSM11918. Accordingly LB931 may be used for treating and/or preventing urogenital infections. LB931 can advantageously be included in pharmaceutical compositions and in products for personal care, such as diapers and sanitary napkins.--.

IN THE CLAIMS:

Claim 1 has been amended as follows:

--1. (amended) A biologically pure strain of *Lactobacillus plantarum*, strain LB931, which has been deposited at Deutsche Sammlung von Mikroorganismen, and been assigned accession number DSM11918.--

Claim 4 has been amended as follows:

--4. (amended) A pharmaceutical composition according to claim 3, [characterised in that it also comprises] further

comprising other lactic acid bacteria.--

Claim 5 has been amended as follows:

--5. (amended) A pharmaceutical composition according to claim 3 comprising  $10^4$  to  $10^{11}$  [cfu] colony-forming units, [preferably  $10^5$  to  $10^9$  cfu,] LB931.--

Claim 7 has been amended as follows:

--7. (amended) An absorbent product[, such as a feminine hygiene product, diaper, sanitary napkin, panty guard or an incontinence guard, characterised in that it comprises] comprising *Lactobacillus plantarum*, strain LB931, which has been deposited at Deutsche Sammlung von Mikroorganismen, and been assigned accession number DSM11918.--

Claim 8 has been amended as follows:

--8. (amended) An absorbent product according to claim 7, comprising  $10^4$  to  $10^{11}$  cfu, [preferably  $10^5$  to  $10^9$  cfu,] LB931.-

Claim 9 has been amended as follows:

--9. (amended) A pharmaceutical composition according to claim 5 wherein said pharmaceutical acceptable carrier is [skimmilk] skimmed milk or a lactobacillus growth factor in powder or other form.--

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